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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/980,593 | 12/04/2001 | Howard Tucker | P 0284115 | 6323 |

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PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

| EXAMINER | |
|---|---|
| HABTE, KAHSAY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1624 | |

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/980,593 | TUCKER, HOWARD | |
| | Examiner | Art Unit | |
| | Kahsay Habte, Ph. D. | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6* is/are allowed.

6)☒ Claim(s) *8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-6 and 8 are pending.

### *Response to Amendment*

2. Applicant's amendment filed 7/26/04 in response to the previous Office Action (3/25/2004) is acknowledged. Rejections of claim 8 under 35 U.S.C. § 112, first and second paragraph (items 3 and 4) have been maintained.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited a method of treating a metalloproteinase mediated disease selected from the group consisting of matrixmetalloproteinase, collagenases, gelatinases, stromelysins, matrilysin, metalloelastase, enamelysin, and MT-MMPs, but the specification is not enabled for such a scope. According to the specification on page 1, there are about 26 MMP's that are associated with many disease conditions.

Applicants are claiming the treatment of all metalloproteinase mediated diseases that is contrary to the current medical practices. For example, on page 1 of the specification it has been disclosed the treatment of various tumors, and inflammatory diseases that are hard to treat (see item 3 of the previous Office Action for details).

***Response to arguments***

Applicant's argument filed 07/26/2004 has been fully considered but it is not persuasive.

Applicants have amended the claim to overcome the rejection, but said amendment does not solve the problem. The examiner suggested that applicants could overcome the rejection by limiting the MMP and by reciting specific diseases that are tied with said MMP (assuming there is support in the specification). Applicant's amendment of claim 8 "metalloproteinase mediated disease is selected from the group consisting of matrixmetalloproteinase, collagenases, gelatinases, stromelysins, matrilysin, metalloelastase, enamelysin, and MT-MMPs" does not overcome the rejection. Applicants did not address the issue, since they have not shown any evidence or argue the rejection that deals with a method of treating a metalloproteinase mediated disease condition generally. Applicants simply listed different enzymes that are MMPs, instead of reciting specific diseases tied to specific MMP (e.g. a method of treating MMP-13 mediated disease selected from pain, arthritis...) for which they have support in the specification. Matrixmetalloproteinase, collagenases, gelatinases, stromelysins, matrilysin, metalloelastase, enamelysin, and MT-MMPs are not

metalloproteinase mediated disease conditions, but these are proteinases (enzymes). Note that metalloproetinases are superfamily of proteinases (see page 1 of the specification). For example, stromelysins are enzymes and are called MMP-3 (matrix metalloproteinase-3), MMP-10, or MMP-11; matrilysin (MMP-7); metalloelastase (MMP-12); colagenases (MMP-1, MMP-8, or MMP-13); gelatinases (MMP-2 or MMP-9); enamelysin (MMP-19); and the MT-MMPs (MMP-14-17). Since applicant's amendment did not address the issue raised in previous Office Action, the enablement rejection is maintained.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 8, there has been recited "a method of treating a metalloproteinase mediated disease condition." The scope of claim 8 is unknown. There is no standard list of such diseases. Which diseases are these? Are there any that are definitely not included? Determining whether a given disease responds or does not respond to such mediator will surely involve undue experimentation. Suppose that a given inhibitor X when administered to a patient with Disease D does not obtain a response. Does one then conclude that Disease D does not fall within this claim? Keep in mind that:

A. It may be that the next patient will respond. It is quite common for pharmaceuticals to work only with some people, not all. Thus, how many need to be tested?

B. It may be that the wrong dosage or dosage regimen was employed. It is quite common for pharmaceuticals to work at one dosage, but not at another which is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? Thus, how many dosages and dosage regimens must be tried before one is certain that this pharmaceutical won't affect Disease D?

C. It may be that X simply isn't potent enough for Disease D, but that another inhibitor Y is potent enough, so that D really does fall within the claim. Thus, how many different mediators must be tried before one concludes that D doesn't fall within the claim?

D. Conversely, if D responds to Y but not to X, can one really conclude that D falls within the claim? It may be that the X result is giving the accurate answer, and that the success of Y arises from some other unknown property which Y is capable of. Thus, when mixed results are obtained, how many more pharmaceuticals need be tested?

E. Finally, suppose that X really will work, but only when combined with Z. There are for example, agents in the antiviral and anticancer technology which are not themselves effective, but the disease will respond when the agents are combined with something else.

F. In addition, literally speaking, any disorder can be treated with any drug, although the treatment might not be successful. Assuming that "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Note that there are about 26 MMP, thus, each test would be done for all 26 MMP's.

As a result, determining the true scope of the claim will involve extensive and potentially open-ended research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

***Response to arguments***

Applicant's argument filed 07/26/2004 has been fully considered but it is not persuasive.

Please see above (paragraph 3) for details.

b. In claim 8, the phrase "metalloproteinase mediated disease is selected from the group consisting of matrixmetalloproteinase, collagenases, gelatinases, stromelysins, matrilysin, metalloelastase, enamelysin, and MT-MMPs" is incorrect. Matrixmetalloproteinase, collagenases, gelatinases, stromelysins, matrilysin, metalloelastase, enamelysin, and MT-MMPs are category of enzymes and not metalloproteinase mediated disease conditions. See page 1 (lines 10-18) of the specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

Mark L. Berch
Primary Examiner
Art Unit 1624

KH
August 10, 2004